AUG 1 3 2003

510(k) Summary

iVent™ 201 Portable Ventilator with Non-invasive Pulse Oximeter

510(k) Number K021981

Submitter's Name:

VersaMed Ltd.
Hasharon I ndustrial Park,
Ornat Bkdg, P.O.B. 5011,
Kadima 60920, Israel

Contact Person:

Ken Raichman
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Hasharon Industrial Park,
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Kadima 60920, Israel

Tel: 972-9-899 7775
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Trade Name:

iVent™ 201 Pulse Oximeter

Classification Name:

Non-invasive Pulse Oximeter

Classification:

The FDA has classified these devices as a class II device (product code **74 DQA**) and are reviewed by the Anesthesiology, Respiratory, and Defibrillator Devices Group.

Predicate Devices:

The Non-invasive Pulse Oximeter for the *iVent™ 201 Portable Ventilator* is substantially equivalent to:

- MASIMO CSD-1050, 510(k) - Masimo Set 2000, cleared under K990966

Performance Standards:

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, to the best of our knowledge, the ***Non-invasive Pulse Oximeter,*** complies with the following voluntary standards:

- ISO 9919 Pulse Oximeters for Medical Use – Specifications;
- UL 544 Standard for Medical and Dental Equipment; Council Directive 93/42/EEC;
- IEC 601-1-4 Medical Electrical Equipment – Programmable electrical medical systems;
- EN 865 Pulse Oximeters – Particular Specifications.

Versamed's iVent 201 with integrated Pulse Oximetry is designed to meet the FDA recognized Medical Safety standard IEC 60601-1 and the voluntary Pulse Oximetry standards ISO 9919 and EN 865.

Acceptance Criteria and Risk Analysis:

Acceptance criteria for compliance with the standards is detailed in Section 3, part E (Compliance).

Risk Analysis is addressed in Section 5 for hardware and Section 7 for Software.

The hardware risks addressed are leakage current, SpO2 power source failure, SpO2 Alarms and EMC interference. EMC interference is considered from three points: interference of the Ventilator on the Pulse Oximeter, which is checked by Masimo; interference of the Pulse Oximeter on the Ventilator which is checked Versamed's software validation procedure; and interference of the integrated unit on external devices and vise versa, which is checked by an independent accredited testing agent.

The software risks addressed are loss of communication and out of range inputs. These are checked as part of Versamed's Software Test Procedure for validation of the software.

Indication for Use:

The Non-invasive Pulse Oximeter is intended for non-invasive monitoring of oxygen saturation and pulse rate of adult and pediatric patients.

Device Description:

The Non-invasive Pulse Oximeter board, MS-5, connects to sensors and provides oxygen saturation, pulse rate, pulse waveform, and other output information via a serial digital interface. The iVent201 provides DC power and isolates the board from the mains power and ground.

Substantial Equivalence:

The MASIMO MS-5 Board is considered to be substantially equivalent to its predicate device (Masimo SET 2000, cleared under K990966) and cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2003

Mr. Ken Raichman
Vice President of Quality Assurance and Director of Regulatory Affairs
VersaMed Limited
Hasharon Industrial Park
P.O. Box 5011, Ornat Building
Kadima, 60920
ISRAEL

Re: K021981
Trade/Device Name: iVent 201 Portable Ventilator with Pulse Oximeter
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: II (Two)
Product Code: NOU, CBK, DQA
Dated: May 12, 2003
Received: May 15, 2003

Dear Mr. Raichman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

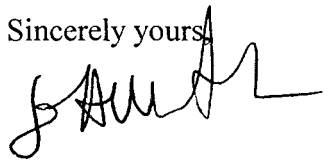
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for, Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K021981

Device Name: **iVent201 Portable Ventilator**

Indications for Use:

The *iVent™ 201* is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lb.), who require the following general modes of ventilatory support, as prescribed by an attending physician:

- Assist/Control (Pressure Controlled or Volume Controlled)
- SIMV (Pressure Controlled or Volume Controlled)
- CPAP/PSV

The *iVent™ 201* ventilator with Non-invasive Pulse Oximeter is suitable for inter-hospital use, home and alternate-site use, transport and emergency use. The Non-invasive Pulse Oximeter is intended for non-invasive monitoring of oxygen saturation and pulse rate.

The *i™ 201* ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician and within the technical specification limits.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(Division Sign-off)
~~Division of Cardiovascular, Respiratory, and Neurological Devices~~

510(k) Number: K021981

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Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)